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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,613	11/28/2000	I. Lawrence Greenfield	7414.0022	7659
22852	7590	11/08/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			RILEY, JEZIA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,613

Applicant(s)

GREENFIELD, I. LAWRENCE

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 and 90-113 is/are pending in the application.
- 4a) Of the above claim(s) 26-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9-13,15-19,23-25,88,91-94,97-101,103-107 and 111-113 is/are rejected.
- 7) ☒ Claim(s) 2,7,8,14,20-22,90,95,96,102 and 108-110 is/are objected to.
- 8) ☒ Claim(s) 1-88 and 90-113 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/04 has been entered.

Response to Remarks

2. Applicants' amendments, filed on 7/15/04, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18, 19, 24, 25, 106, 107, 112, 113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24 and 112 recite the limitation "wherein the at least one deoxyribonuclease inhibitor". There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "where in the at least one ribonuclease inhibitor". There is insufficient antecedent basis for this limitation in the claim.

Claims 106 and 107 recites the limitation "where in the at least one ribonuclease inhibitor". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 9-13, 15-17, 23-25, 88, 97-101, 103, 104, 111-113 are rejected under 35 U.S.C. 102(b) as being anticipated by Hewitt (US 4,900,677).

Hewitt discloses a procedure for isolating high molecular weight nucleic acids utilizing a mixture of lytic enzymes and a chaotropic agent to complete protein denaturation and dissociation from nucleic acids (see entire document).

The reference discloses method of isolating nucleic acids, particularly DNA, from their source organism. By source organism is meant any organism which contains a nucleic acid, including cells, particularly microbial cells, viruses, and mycoplasma. The cells subjected to this process include cells of mammalian or bacterial origin or a

mixture of mammalian and bacterial cells. This improved method allows rapid, high yield recovery of high molecular weight nucleic acids from a wide variety of source organisms especially from most clinically relevant cell types. Surprisingly, it has been found that the method of this invention allows isolation of high molecular weight nucleic acids from a very wide variety of organisms in approximately 90 minutes. This method is expected to find the greatest utility in the isolation of DNA, but is also useful in isolating RNA. The process comprises variety of buffers, including sodium borate and sodium phosphate, but tris(hydroxymethyl)aminomethane hydrochloride (Tris) is preferred. The preferred buffer concentration is 10 mM, although a concentration from about 1 mM to about 500 mM is acceptable. The preferred pH is about 8 although a pH ranging from about 4 to about 9 is acceptable. The buffer can also contain 1-500 mM sodium chloride with 10 mM being preferred and, similarly, about 1-10 mM ethylenediaminetetraacetic acid (EDTA),[which is viewed to be inclusive of instant claim 17 and 23 for example, (see instant specification page 11, for the definition of chelator)], with about 1 mM being preferred. The preferred buffer composition is 10 mM Tris, 10 mM sodium chloride, 1 mM EDTA, pH 8.0 (Tris buffer, pH 8.0). The process can be readily adapted to accommodate larger volumes and/or different numbers of cells by adjusting dilutions and process timing. (col.5). Complete lysis of the cells can be assured by addition of surfactant to the lytic mixture, increasing the temperature of lysis and/or by using a longer reaction time. The surfactant addition can be prior to, simultaneous with or subsequent to the lytic enzyme treatment. It is generally preferred to add sodium dodecylsulfate (SDS) to a final concentration of about 0.1% (w/v) and to increase the

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temperature to about 60 °C. for 10 minutes. Other surfactants can be utilized. These include cationic, anionic and nonionic surfactants such as Triton X-100, octyl-.beta.-D-glucopyranoside, 3-[(3-cholamidopropyl)dimethylammonio]-1-propane sulfonate (CHAPS) and 3-[(3-cholamidopropyl)dimethylammonio]-2-hydroxy-1-propane sulfonate (CHAPSO). The cellular proteins present in the lytic mixture and the RNase can then be degraded with a non-specific protease or a mixture of such broadly active proteases. The preferred protease is Proteinase K, but others such as an alkaline protease isolated from *Streptomyces griseus* can be substituted. The final concentration is preferably 50-500 .mu.g/mL for about 5-120 minutes at about 20-70°C. A preferred specific treatment condition is approximately 300 .mu.g/mL of Proteinase K at approximately 60° C. for approximately 30 minutes. Which is viewed to be inclusive of the thermostable protease (col.7).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 3-6, 9-13, 15-17, 23-25, 88, 91-94, 97-101, 103-105, 111-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hewitt in view of Lienau et al. (US 6,548,256).

Hewitt is discussed above

Lienau discloses a method and kit for isolating nucleic acids from a nucleic acid containing starting material, where the nucleic acids are released from the starting material and precipitated onto a trapping membrane. The method and kit may be used in the context of isolating genomic DNA from blood and isolating BACs from transformed bacterial cultures. One method includes mixing the starting material with a lysing and denaturing substance for release of the nucleic acid from the starting material. The lysing and denaturing substance of the invention causes the release of the nucleic acids from the intact cells of the starting material. Typically, the lysing and denaturing substance includes a buffering agent, a salt, a detergent and a protease which is viewed to be inclusive of instant claims 12, 13, 100 and 101. (Col. 6, lines 60-65). In preferred embodiments of the lysing and denaturing substance, the salt is NaCl, NaOAc, KOAc, NH₄ Cl, and the like, or mixtures thereof. The detergent is a quaternary

amine cationic detergent, for example, cetyltrimethylammonium bromide (CTAB), and the like, and mixtures thereof, and the protease is Proteinase K.(col. 7 and example 1). Therefore it would have been obvious at the time the invention was made to use the surfactant of Lienau for the method of Hewitt. Hewitt discloses that complete lysis of the cells can be assured by addition of surfactant. Further Hewitt adds that "Other surfactants can be utilized. These include cationic, anionic and nonionic surfactants, which is viewed to be inclusive of the surfactant of Lienau et al.

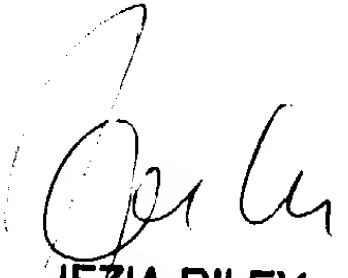
9. Claims 2, 7, 8, 14, 20-22, 90, 95, 96, 102, 108-110 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, November 04, 2004



JEZIA RILEY
PRIMARY EXAMINER